

**Catheter for aspirating, fragmenting and removing
removable material from blood vessels**

The invention relates to a catheter for aspirating,
5 fragmenting and removing removable materials from
hollow bodies, in particular thrombi and emboli from
blood vessels, comprising a working head which is
axially displaceable over a guide wire independently
thereof and is arranged at the distal end of the
10 catheter and which has at least one lateral opening,
the catheter having a flexible transport screw which
can be caused to rotate by means of a rotary drive of a
drive unit remote from the working head, and comprising
a flexible tube surrounding the transport screw,
15 connected to the working head and intended for removing
the detached thrombi and emboli fragments and a cutting
tool.

Such catheters are used in particular for the treatment
20 of occlusive arterial diseases by aspiration,
fragmentation and removal of emboli and thrombi. They
are introduced into the artery or vein and advanced,
preferably with X-ray monitoring, up to the narrowed or
blocked area which is to be treated. A fragmentation
25 tool drivable in a rotary manner by means of a rotary
drive, and a working head, are arranged at their front
or distal end.

In the case of these catheters, a distinction should be
30 made as a rule on the basis of two different fields of
use:

A) Atherectomy

This is the removal of, as a rule, hard deposits which have adhered to the vessel walls over many years.

B) Thrombectomy

- 5 This is the removal of fresh blood clots which accumulate at bottlenecks and lead to blockage of the blood vessels (emboli).

A rotational catheter disclosed, for example, in EP 0
10 267 539 B1 and intended for atherectomy has, as a cutting tool, a substantially ellipsoidal cutter whose surface is provided with abrasive material and which is driven via a flexible drive shaft by a rotary drive
15 arranged at the proximal end of the catheter at a speed of up to 160 000 rpm. The cutter is connected to the flexible drive shaft. The drive shaft runs in a tubular sheath serving as a catheter tube. A guide wire which is introduced into a blood vessel before the
20 introduction of the catheter and is advanced to the area to be treated or slightly beyond and serves as a guide for the cutter and the drive shaft extends through the drive shaft.

In the case of these known rotational catheters, the
25 risk that the vessel wall will be injured and in certain circumstances even perforated, particularly in pronounced curves of the blood vessel, cannot be ruled out.

30 A further rotational catheter disclosed in US 5 571 122 A has a cutting tool with a multiplicity of peeling knives extending in the axial direction and driven at a speed of about 800 rpm. By axial compression of the

cutting tool, the peeling knives can be caused to bulge radially outward and the external diameter of the cutting tool is thus increased. In the case of this catheter, there is the risk that, particularly as a
5 result of the relatively slow circumferential speed, the peeling knives may pull, drag or jam against the vessel wall, with the result that the blood vessels react dramatically in that they contract and thus prevent further intervention.

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US 5 226 909 discloses another atherectomy catheter which has, on its working head, a sleeve-like or helical cutting element drivable by a rotary drive and/or displaceable in the axial direction. The
15 opening of the working head is pressed against the deposits adhering to the vessel wall by means of a lateral inflatable balloon. These deposits are then comminuted by rotation or axial advance of the cutting element and are collected in a chamber. The chamber
20 must then be emptied from time to time by withdrawing the catheter. Continuous removal of comminuted deposited material is not envisaged.

WO 96/29941 A1 describes a rotational catheter for
25 atherectomy, whose working head consists of a stationary stator, connected to a tube, and a rotor. The rotor is rotatable relative to the stator by means of a high-speed transport/drive screw. Both the stator and the rotor have, at their circumference, windows
30 which can be caused to coincide. As a result of shearing between a cutting edge on the rotor and an opposite cutting edge on the openings of the stator, comminution of the parts projecting into or sucked into

the openings is effected. The rotor may surround the stator on the outside ("outer rotor") or may be arranged in the interior of the stator ("inner rotor").

- 5 Catheters having inner and outer rotors with cutting edges which operate around the catheter axis have the disadvantage that they stir up blood and occlusion material, so that the blood flow from proximal to distal may wash away particles which may again produce
10 blockages and blood flow problems in other areas of the blood circulation, particularly in small blood vessels.

Further documents relating to the prior art are: EP 0 310 285 A2; EP 0 448 859 A2, EP 0 669 106 A2, EP 0 680
15 730 A2, EP 0 669 106 B1, EP 0 739 603 A1, WO 02/49690 A2, US 4, 857,046 and US 5,100,426.

Rotational catheters known to date and comprising revolving knife-like elements or cutters require a
20 relatively powerful rotary drive which in turn necessitates a more powerful rotationally more rigid catheter tube for compensating the moment of reaction which arises during cutting of particles, in order that the catheter tube does not rotate about the
25 longitudinal axis. However, a stronger or rotationally more rigid tube is inevitably less flexible, with the result that the catheter is in certain circumstances disadvantageous in the curves of blood vessels.

30 It is the object of the invention to provide a catheter of the type mentioned at the outset, in particular for thrombectomy, which has no externally revolving cutting knife, cutter or the like, operates in a atraumatic

manner and can aspirate and fragment thrombi and emboli in the blood vessel and transport them through the catheter tube continuously out of the vessel.

5 It is therefore intended to achieve a reduction in components and to minimise the risk of injury to walls of blood vessels. The advantages of known systems, in particular those of the system according to WO 96/29941 A1 are however to be retained.

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According to the invention, the object is achieved if the transport screw in the region of the working head is in the form of a shearing cutting tool cooperating with the opening of the working head in order
15 continuously to comminute the penetrating materials or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings. The transport effect of the transport screw is retained as in the design according
20 to WO 96/29941 A1.

The transport screw thus performs an additional function, namely the comminution of the deposit particles and tissue particles aspirated in the
25 transport direction into the openings by the action of the reduced pressure. In contrast to the prior art, this comminution takes place not rhythmically when cutting edges come into contact with one another but continuously. The internally rotating and internally
30 cutting transport screw in the working head aspirates and comminutes the deposits without causing vortices outside. The risk that particles will be washed away and that there will be blood flow disturbances distally

due to catheter intervention is therefore absent.

There are also virtually no vibrations, which in principle it is wished to avoid in the case of blood
5 vessels. Since a lower reaction torque is necessary as a result of the continuous cutting, the tube may also have a thinner wall and be more elastic. This is also the case in particular because the cutting force generated during fragmentation acts mainly in the axial
10 direction (proximally) and not, as in the prior art described, in the circumferential direction. The torsional load of the tube is therefore very small.

The working head is preferably, and as known per se,
15 cylindrical, one or more window-like openings, such as bores or shaped slots, being arranged at the circumference. As a result of the cooperation of the transport screw rotating at high speed and the inner wall of the cylindrical working head, or with the edges
20 of the openings, the result is a rotary cutting tool which provides good fragmentation power with a relatively low torque or low drive power.

Compared with the prior art disclosed in WO 96/29941
25 A1, at least one of the components of the working head, namely the rotor, is omitted. This leads to a simplification and cost reduction. Furthermore, because of the lack of a rotor, jamming between rotor and stator cannot occur. In addition the design
30 according to the invention permits the reduction of the external diameter to small dimension not realizable to date. Such small dimensions are required, for example, for the treatment of coronary vessels.

The transport screw is expediently formed, in the region of the working head, as a shearing cutting tool which cooperates with the opening of the working head and, in the operating state, continuously comminutes the penetrating materials or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings and removes said materials or thrombi or emboli along the transport surface in the direction of the proximal end.

The transport screw is, in the region of the working head, advantageously in the form of a shearing cutting tool which cooperates with the opening of the working head and, in the operating state, continuously comminutes the penetrating material or aspirated and/or detached thrombi and emboli between the peripheral borders of the transport screw and borders of the openings and removes said materials or thrombi or emboli along the transport surface, and the lateral opening of the working head is in the form of an L-shaped slot having a limb extending substantially in the longitudinal direction and a limb extending along a part of the circumference. The thrombi and emboli to be removed can therefore be drawn in or sucked along the limb extending in the longitudinal direction into the interior of the working head and then sheared off by means of the transport screw at the proximal edge of the limb extending in the circumferential direction.

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The ratio of the width of the limb extending in the longitudinal direction to the width of the limb extending in the circumferential direction is from 1.0

to 1.3. Thus, good transport of the aspirated thrombi and emboli in the direction of the proximal end and subsequent clean shearing off are permitted.

5 The distal part of the transport screw, in the region of the working head, is formed in the external diameter to be an exact fit with the internal diameter of the preferably cylindrical working head, so that the external diameter of the transport screw results in
10 only minimal diameter play relative to the inner lateral surface of the working head. This prevents fragmented elements from being able to become jammed between the transport screw and the internal diameter of the working head.

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The edges on the outside of the transport screw are advantageously formed so as to be sharp in the region of the opening of the working head. This permits a good and clean shearing off of generally very tough
20 thrombi and emboli to be removed.

The working head is expediently tapered toward its distal end. This ensures that the catheter can also be advanced by sliding in narrow radii of curvature of the
25 vessels without great resistance. Thus, it cannot become hitched to the vessel wall or to projections.

The edges of the lateral openings are advantageously formed to be sharp at least in regions on the inside.
30 This together with the periphery of the transport screw permits a clean shearing process for fragmenting the thrombi or emboli. The openings of the catheter head are designed so that the transport screw rotating at

high speed fragments thrombi and emboli which are aspirated at the inner sharp edges of the openings and the outer diameter of the transport screw to form pieces. These pieces are transported in the direction
5 of the rotary drive by the prevailing suction and the screw transport.

The edges of the lateral opening are rounded, expediently at least in regions, on the lateral surface
10 of the working head. This permits vortex-free flow of the deposits to be removed and of other body fluids in the region of the working head.

The lateral opening in the working head is
15 advantageously in the form of a slot. Slots can be easily produced and can be adapted to requirements in their dimensions.

It is expedient if the slot runs at least partly in the
20 axial direction of the working head. By changing length and width, the slot can be adapted according to the different requirements of the different applications.

25 An advantageous embodiment consists in the slot being formed, relative to the longitudinal axis of the working head, at least partly along a helix. Optimum adaptation to the respective circumstances is also possible by means of the helix angle or the direction
30 of rotation of the helix. The direction of rotation of the helix can be identical to or different from the direction of rotation of the transport screw. An identical direction of rotation gives a drawn out cut

over a larger cutting length. This is advantageous in particular for tough or fibrous material to be removed. An opposite direction of rotation gives a short cut and tends to be suitable for brittle material.

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For certain applications, it is expedient if the width of the slot decreases toward the proximal end of the working head. The deposits sucked in to the slot, such as thrombi or emboli, are thus forced toward the proximal end against a bottle neck, which permits improved fragmentation of the deposits.

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An advantageous embodiment consists in forming the slot as an L-shape. The slot may consist, for example, of a part running in the axial direction and a part connected to this and running in the circumferential direction.

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Expediently, at least one groove-like recess starting from the distal end and opening into the lateral opening is formed in the distal end region of the working head. This groove-like recess forms a channel through which thrombi, emboli and/or other deposits can therefore also be aspirated from the distal end, can reach the region of the lateral opening and can be comminuted by the cooperation of the transport screw with the working head.

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It is advantageous if the depth of the groove-like recess increases toward the proximal end of the working head. This can be achieved on the one hand if the working head tapers toward the distal end or if the base surface of the recess is arranged so as to be

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inclined relative to the longitudinal axis of the working head. As a result of the increasing depth, the flow cross-section is increased toward the proximal end and hence the deposits are more easily transported
5 away.

The width of the groove-like recess is expediently greater than the chord of the internal diameter of the working head in the region of the groove base. This
10 gives rise to clean edges, along which the deposits are sucked into the interior of the working head in order to be subsequently fragmented there.

The working head is advantageously connected to the
15 tube axially so as to be resistant to tension and pressure. Since in practice only a small reaction torque is exerted on the tube, in contrast to the prior art, the requirements with regard to the connection between the working head and the tube and with regard
20 to the torsional rigidity of the tube itself are relatively low so that, for example, a simple press-fit or adhesive connection is possible and the tube may be very elastic.

25 As a result of the flow caused by the transport screw, reduced pressure results in the tube. In order to increase the flexibility of the tube, it is expedient if the tube has a reinforcement at least in sections. As a result of the reinforcement, the wall thickness of
30 the tube can also be kept thinner and the flexibility can thus also be increased. A reinforcement also has a stabilizing effect on the play between the inner wall of the tube and the external diameter of the transport

screw.

The reinforcement is advantageously in the form of a metallic helix. Such a helix has a high flexibility in the bending direction and good tensile and compressive strength.

For production and also for use during insertion of the catheter, it is expedient to arrange the reinforcement on the inside of the tube. This permits a smooth surface on the outside of the catheter. However, the reinforcement can also be embedded completely in plastic.

An advantageous embodiment consists in forming the tube in two parts, the proximal part being in the form of a pure plastic tube and the distal part facing the working head being in the form of a metallic helical spring having a thin-walled elastic plastic sheath. Thus, the distal part of the tube is particularly flexible and the catheter can be advanced and withdrawn virtually without effort even around narrow curves.

The working head and/or the transport screw expediently consist of metal. In particular, stainless steels or other corrosion-resistant alloys are suitable.

With regard to improved material properties, the working head can alternatively also be composed of sintered ceramic or metal ceramic or have a highly resistant layer for protection from wear.

Further developments of the invention and variants

thereof are indicated in the dependent patent claims and in the figures and the description of the drawings.

It is true that in the above text reference is made to
5 a catheter for aspiration, fragmentation and removal,
in particular from human blood vessels; however, the
invention is not limited thereto but rather is also
available to other users for analogous applications in
the medical sector (e.g. reopening occluded organ
10 regions, such as, for example, ureter, bile duct or
fallopian tube and vascular prostheses and so-called
stents). The patent claims should accordingly be
interpreted broadly.

15 The list of reference numerals and the drawing together
with the subject matter described or protected in the
claims, form integral parts of the disclosure of this
Application.

20 **Description of figures**

The figures are described in relation to one another
and overall. Identical reference numerals denote
identical components, and reference numerals with
25 different indices indicated functionally identical
components.

The figures show the following by way of example:

30 Fig. 1 shows the schematic overall setup of a
device having a catheter according to
the invention;

- Fig. 2 shows a view of the working head of a catheter according to fig. 1;
- Fig. 3 shows the working head according to fig. 2, in longitudinal section;
- Fig. 4 and 5: show a variant of the working head in perspective view;
- Fig. 6 to 10: show a variant of the working head with a rectangular lateral opening;
- Fig. 11 to 15: show a variant of the working head according to fig. 6 to 10, with a narrow slot extending in the longitudinal direction;
- Fig. 16 to 20: show a variant of the working head with an approximately square lateral opening;
- Fig. 21 to 25: show a variant of the working head with a slot-like opening extending in the circumferential direction;
- Fig. 26 to 30: show a variant of the working head with a groove-like recess starting from the distal end and opening into the lateral opening;
- Fig. 31 to 35: show a variant of the working head with a lateral opening in the form of a longitudinal slot and a groove-like recess starting from the distal end and

opening into the lateral opening;

Fig. 36 to 40: show a variant of the working head with
an approximately triangular lateral
opening whose width tapers toward the
proximal end;

Fig. 41 to 45: show a variant of the working head with
a lateral opening which consists of a
region extending in the axial direction
and a region extending over a part of
the circumference;

Fig. 46 to 50: show a variant of the working head
analogously to fig. 41 to 45, the region
extending over a part of the
circumference running in the opposite
direction;

Fig. 51 to 55: show a variant of the working head
analogously to fig. 41 to 45, the region
extending in the longitudinal direction
being substantially longer;

Fig. 56 to 60: show a variant of the working head
analogously to fig. 51 to 55, the region
extending over a part of the
circumference running in the opposite
direction according to the setup
according to fig. 51 to 55;

Fig. 61 to 65: show a variant of the working head with
a lateral opening extending along a

helix;

Fig. 66 to 70: show a variant of the working head
analogously to fig. 61 to 65, that
5 region of the opening which runs along a
helix opening at the distal end into a
region running in the axial direction;

Fig. 71 to 75: show a variant of the working head
10 analogously to fig. 66 to 70, that
region of the opening which runs along a
helix being oriented in the opposite
direction of rotation and

15 Fig. 76 to 80: show a variant of the working head
analogously to fig. 66 to 70, a groove-
like recess starting from the distal end
opening into the opening running along a
helix.

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Fig. 1 schematically shows the overall setup of a
medical device for use of the catheter according to the
invention. The device has a drive unit 1 with a rotary
drive 2. An injection chamber 3 is present at the
25 front end of the rotary drive. This is connected via a
removal channel 4 to a collecting container 5. A guide
wire 6 passing through the drive unit has a proximal
(rear) end 7 and a distal (front) end 8. A movable
insertion lock 9 is located upstream of the injection
30 chamber 3. This setup corresponds substantially to
that of WO 96/29941 A1. Design details can also be
taken over from there.

A catheter designated as a whole by 10 substantially comprises a flexible tube 12 and a working head 11 connected thereto in a manner resistant to tension and pressure. The guide wire 6 passes through the catheter 10, the distal end 8 projecting beyond the working head 11.

The working head 11a visible in fig. 2 and 3 and shown on a larger scale and partially in section has a lateral opening 14a. A helical transport screw 13 surrounds the guide wire 6 and is matched in external diameter exactly to the internal diameter of the working head 11a. The opening 14a has an inner edge 15 which is sharp and an outer border 16 which is rounded. At the edge 15, the deposits which are sucked by the reduced pressure generated by the transport screw 13 into the interior of the working head 11a are fragmented by shearing off by the periphery of the transport screw 13 which cooperates with the edge 15 and are transported by means of the transport screw 13 in the direction of the drive unit 1 through the tube 12.

The section shown in fig. 3 shows the setup of the tube 12. This preferably consists of a reinforcement 17 wound, for example, from a fine wire and a thin plastic sheath 18. This setup gives very high flexibility of the tube 12, which is advantageous particularly in the distal region of the catheter 10. For production and cost reasons, the proximal region of the tube can also be in the form of a customary thicker plastic tube, it being possible for the two regions to be connected to one another, for example, by shrinkage or adhesive

bonding. One variant comprises the joint covering of the reinforcing tube and of the connecting proximal part of the tube with a thin, closely fitting covering.

5 The working head 11b shown in fig. 4 and 5 has an opening 14b which substantially comprises a longitudinal slot 20 and a circumferential slot 21 extending along a part of the circumference. A groove-like recess 19a starting from the distal end opens into
10 the longitudinal slot 20. This formation makes it possible to handle the deposits in front of the working head 11b. The working head 11b tapers toward the distal end. This facilitates the advance of the catheter in the duct or blood vessel to be freed from
15 obstruction.

Fig. 6 to 80 show different variants of the formation of the lateral opening in the working head. However, these diagrams are not limiting but are to be
20 understood merely by way of example. Further embodiments and also combinations of the formations shown are conceivable.

List of reference numerals

- 1 Drive unit
- 2 Rotary drive
- 3 Injection chamber
- 4 Removal channel
- 5 Collecting container
- 6 Guide wire
- 7 Proximal end
- 8 Distal end
- 9 Insertion lock
- 10 Catheter
- 11a, 11b, 11c, 11d, 11e, 11f, 11g, 11h, 11i, 11k, 11l,
11m, 11n, 11o, 11p, 11q
Working head
- 12 Tube
- 13 Transport screw
- 14a, 14b, 14c, 14d, 14e, 14f, 14g, 14h, 14i, 14k, 14l,
14m, 14n, 14o, 14p, 14q
Opening
- 15 Edge
- 16 Border
- 17 Reinforcement
- 18 Sheath
- 19a, 19b, 19c Groove-like recess
- 20 Longitudinal slot
- 21 Circumferential slot